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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,397	03/09/2004	Robert Falotico	CRD-5068	1881

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
HAGOPIAN, CASEY SHEA	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,397	FALOTICO ET AL.	
	Examiner	Art Unit	
	Casey Hagopian	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *12-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 11/15/2007.

Claim 9 is amended and claims 12-24 have been withdrawn. Thus, claims 1-11 are currently under consideration.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 8/22/2007:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims1-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borges et al. (US 2005/0033417 A1) in view of Fischell et al. (US 2003/0065382 A1).

Borges teaches coating an implantable medical device with a composition comprising a basecoat and a topcoat, wherein the basecoat includes at least one active agent that is incorporated into a first polymeric material, the basecoat is affixed to the surface of the medical device, and the topcoat contains a second polymeric material which is affixed to the basecoat for the purpose of controlling the elution rate of the at least one active agent (paragraph 0027). Borges teaches a particular embodiment where the basecoat comprises a fluoropolymer and rapamycin and the topcoat comprises an acrylic polymer (paragraph 0030). Borges also teaches the particular medical devices, stents, anastomosis devices and stent-grafts (abstract; paragraph 0032). Borges further discusses drug combination therapy mainly for the treatment of restenosis and lists possible drugs that may be employed in the invention including rapamycin, cladribine and etoposide (paragraphs 0085-0087).

Borges is silent to the particular drug combination of rapamycin and a topoisomerase I inhibitor.

Fischell teaches a stent that is coated with a composition comprising a polymer and one or more anti-restenosis drugs selected from the group consisting of a finite amount of particular drugs including topoisomerase I inhibitors including adriamycin etoposide, irinotecan and hycamptin (topotecan) as well as rapamycins (abstract; paragraphs 0020 and 0022).

One of ordinary skill in the art would have been motivated to include any combination of the finite number of anti-restenosis drugs suggested by Fischell because they are all art-recognized equivalents used for the same purpose. Both references teach coating an implantable medical device with a composition comprising anti-restenosis drugs, thus one skilled in the art would readily look to Fischell for other anti-restenosis drugs or combinations of anti-restenosis drugs. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as a topoisomerase I inhibitor and a rapamycin. Thus, in Borges, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular anti-restenosis drug combination of a rapamycin and a topoisomerase I inhibitor such as iriniotecan or topotecan as suggested by Fischell.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Borges et al. (US 2005/0033417 A1) in view of Fischell et al. (US 2003/0065382 A1) and further in view of Wrenn (USPN 6,485,514 B1).

Borges and Fischell teach the elements discussed above. The references are silent to the particular topoisomerase I inhibitor, camptothecin. Wrenn teaches an implantable medical device coated with a composition comprising camptothecin for the treatment of restenosis (claim 1). One skilled in the art would look to Wrenn because Wrenn teaches that camptothecin is an effective compound for treating restenosis via a coated medical device. It is within the knowledge of one skilled in the art to replace one

anti-restenosis drug, or more specifically one topoisomerase I inhibitor, for another because they are art-recognized equivalents used for the same purpose. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as the topoisomerase I inhibitor camptothecin and a rapamycin. Thus, in Borges and Fischell, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include camptothecin as suggested by Wrenn.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borges et al. (US 2005/0033417 A1) in view of Fischell et al. (US 2003/0065382 A1) and further in view of Eury et al. (US 2002/0004679 A1). Borges and Fischell teach the elements discussed above. The references are silent to the particular topoisomerase I inhibitors, camptothecin and DX-8951f. Eury teaches an implantable medical device coated with a composition comprising a topoisomerase I inhibitor for the treatment of restenosis (abstract; paragraph 0045). A preferred topoisomerase I inhibitor is camptothecin and analogues thereof including DX-8951f, iriniotecan and topotecan (paragraphs 0035 and 0036). One skilled in the art would look to Eury because Eury teaches that topoisomerase I inhibitors in general, and camptothecin and its analogues in particular, are effective compounds for treating restenosis via a coated medical device. It is within the knowledge of one skilled in the art to replace one anti-restenosis drug, or more specifically one topoisomerase I inhibitor, for another because they are art-recognized equivalents used for the same purpose. A practitioner would have

reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as camptothecin or an analogue thereof and a rapamycin. Thus, in Borges and Fischell, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include camptothecin or an analogue thereof as suggested by Eury.

Response to Arguments

Applicant's amendment to claim 9 renders the rejection of claims 9-11 under 35 USC 112, 2nd paragraph moot. Accordingly, the said rejection has been withdrawn.

Applicant's arguments with regards to rejections under 35 USC 103 have been fully considered but they are not persuasive. Applicant argues that a) none of the references, alone or in combination, disclose the invention of claim 1 (pages 6-7 of Remarks) and b) the primary reference, Borges, qualifies as prior art under 102(e) but shares a common assignee with the instant application and therefore cannot qualify as prior art under 35 USC 103 (pages 7-8 of Remarks). In response to (a), it is respectfully submitted that applicant fails to comply with 37 CFR 1.111(b) because argument (a) amounts to a general allegation that the references do not teach the claimed invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Thus, said argument is unpersuasive. In response to (b), it is respectfully submitted that that examiner agrees with applicant that Borges and the instant application share a common assignee but have different inventive entities.

However, the MPEP clearly states that the assignment needs to be the same **at the time of the invention** (see MPEP 2136.01(II)). The assignment of the Borges reference was fully executed on 7/19/2004 and the filing date of Borges was 7/1/2004 but claims priority to 7/31/2003 (see attached Patent Assignment Abstract for application 10/883328). The assignment of the instant application was executed on 6/1/2004 and has a filing date of 3/9/2004 (see attached Patent Assignment Abstract for application 10/796397). While the assignee is the same on both applications, there is a lack of evidence that the reference and the instant application were co-owned by the same assignee at the time the invention was made. It is suggested that applicant reference MPEP 2136.05 which describes how to overcome a rejection under 35 USC 102(e). The following excerpt may also prove useful.

> This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

For these reasons, applicant's arguments at this time are unpersuasive. Thus, the rejections under 35 USC 103 are maintained.

Conclusion

All claims have been rejected; no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

Casey Hagopian
Examiner
Art Unit 1615

CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500